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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,208	09/16/2005	Bjarne H Dahl	2815-0299PUS1	7493
2292 7590 09/30/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 09/30/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/526,208	Applicant(s) DAHL ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 and 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election without traverse of group I, claims 22-25 in the reply filed on Jul. 23, 2008 is acknowledged.

Claims 1-20 have been canceled. Claims 22-25 and claims 21, 26, 33-34 reading on A is optionally substituted phenyl, D is tetrazolylphenyl (formula II or III) will be prosecuted. Claims 27-32, 35-39 and the remaining subject matter of claims 21, 26, 33-34 are withdrawn from consideration per 37 CFR 1.142(b).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-26, 33-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Christophersen et al. WO 02/39987 (recited on 1449) supplemented with CA 136:380081, see anticipating structure by CAS.

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Christophersen et al. WO 98/47879 (recited on 1449). See p.27 line 22, p.28 line 13.

Claims 21-26, 33-34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dahl et al. WO 00/24707 (recited on 1449), see p.34-36 claim 6, tetrazolyl phenyl and tetrazolyl-biphenyl species.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-26, 33-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. WO 00/24707 or Christophersen et al. WO 98/47879 in view of Dahl et al. WO 00/24707 supplemented by CA132:308142.

Determination of the scope and content of the prior art (MPEP §2141.01)

The anticipatory species disclosed by Christophersen et al. '879 or Dahl et al. '707 have been clearly pointed out supra. Generically both Christophersen et al. '879 (see p.4-5) and Dahl et al. '707 (see p.6-8) disclosed broadly the instant claimed optional substituents on the N-phenyl, N'-phenyl urea core.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The exemplified compounds of the prior art differ from the species of the instant claims in that mix and matching of optional choices of substituents were not identical. Generically, the two prior art references taught and exemplified sufficient variations as to enable one having ordinary skill in the art to practice the full generic scope. Especially, the Dahl et al. '707 reference exemplified the compounds (See structural delineation by CAS 132) containing the particular limitation of the instant formula II or III for R³-R⁶ or R^g.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in the field of chloride channel binding phenylurea compound art is deemed to be aware of all the pertinent art in the field. The above references placed the operable teaching and specific compounds in the possession of artisan in the field. The modification of one proven compound with attributes of another proven compound, with guidelines taught and well exemplified generically by the references, is prima facie obvious. In absence of unexpected result, there is nothing unobvious in picking some among many. In re Lemin 141 USPQ 814.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21-26, 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,297,261; US 6,706, 749; US 6,696,475 or WO 2004/012733 supplemented with CA 140:175143.

See tetrazolyl compounds of US 6,297,261, claims 3 or 13;

See tetrazolyl compounds of US 6,706,740, claim 6;

See tetrazolyl compounds of US 6,696,475, claim 6.

See anticipatory compounds delineated in CA, WO 04/012733 has a effective filling date of Aug. 1, 2002.

5. Claims 21-26, 33-34 are directed to the same invention as that of claims 3 or 13 US 6,297,261; claim 6 US 6,706,740 or claim 6 of US 6,695,475 all commonly assigned but have different inventorships. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of the identical invention i.e. anticipatory species must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-26, 33-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. US 6,706,749 or US 6,696,475 or Christophersen et al. US 6,297,261 in view of Dahl et al. US 6,706,749 or US 6,696,475 supplemented by CA132:308142.

Determination of the scope and content of the prior art (MPEP §2141.01)

The anticipatory species disclosed by Christopherson et al. '261 or Dahl et al. '749, '475 have been clearly pointed out supra. Generically both Christopherson et al. (see col. 2-3) and Dahl et al. '749 col. 4-8, '475 col. 4-9 disclosed broadly the instant claimed optional substituents on the N-phenyl, N'-phenyl urea core.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The exemplified compounds of the prior art differ from the species of the instant claims in that mix and matching of optional choices of substituents were not identical. Generically, the two prior art references taught and exemplified sufficient variations as to enable one having ordinary skill in the art to practice the full generic scope. Especially, the Dahl et al. '749, '475 references exemplified the compounds (See structural delineation by CAS 132) containing the particular limitation of the instant formula II or III for R³-R⁶ or R^g.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in the field of chloride channel binding phenylurea compound art is deemed to be aware of all the pertinent art in the field. The above references placed the operable teaching and specific compounds in the possession of artisan in the field. The modification of one proven compound with attributes of another proven compound, with guidelines taught and well exemplified generically by the references, is prima facie obvious. In absence of unexpected result, there is nothing unobvious in picking some among many. In re Lemn 141 USPQ 814.

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7. Claims 21-26, 33-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of US 6,297,261; claims 1-18 of US 6,706,749 or claims 1-13 of US 6,696,475. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlapping subject matter between the instant claims and issued claims of each reference. The overlapping subject matter are covered by the differences among the issued claims. Particularly guided by the species claims of the issued patents in view of the generic scope of the base claim for each patent rendered the instant particular limitation for formula II or III in claims 22 or 24 obvious. The more limited substitution on the core of formula II or III are mere picking and choosing of the issued claims guided by the species claims. For example, the instant claim 24 when Rg is piperidinylcarbonyl is encompassed by the generic claim 1 of US 6,696,475 (see col. 28, lines 23-35) and guided by the species of claim 6 (see col. 30 lines 1-3) wherein cyclic amine of (CON(R⁹)₂ with two R⁹ forms ring) would be obvious. The issued generic claims guided by the many species claims would rendered the overlapping scope of the instant claims *prima facie* obvious. Since the three US patents are family of WO 98/47879 or WO 00/24707, delineation under 35 USC 102 and 103 *supra* would be applicable and hereby incorporated by reference whenever applicable to the issued claims. Exhausted listing would not be repeated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 23, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625